K012254

1 of 3

VIII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 16 2001

July 13, 2001

1. Submission Applicant & Correspondent:

Name:	Osteotech, Inc.
Address:	51 James Way Eatontown, NJ 07724
Phone No.:	(732) 544-6231
Contact Person:	Kim Thurman

2. Name of Device:

Trade/Proprietary/Model Name:	VBR™
Common or Usual Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Vertebral Body Replacement Device

3. Devices to Which New Device is Substantially Equivalent:

The VBR™ with the smaller diameter sizes (12 – 16 mm) is substantially equivalent, for the purpose of this 510(k), to the following predicate devices.

Trade/Proprietary/Model Name	Manufacturer
VBR™ (20 – 28 mm diameters)	Ulrich GmbH & Co. KG
OEC/Rezaian Spinal Fixator	Orthopedic Equipment Co, Inc.
DePuy Acromed Stackable	DePuy AcroMed, Inc.

4. Device Description:

The VBR™ is a cylindrically shaped implantable titanium alloy device indicated for use in the thoracic and lumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The VBR™ is also indicated for treating fractures of the thoracic and lumbar spine.

The VBR™ consists of three (3) basic components, at least two (2) of which are threaded, such that the VBR™ is distractible and retractable by means of rotating the center ring or cylinder. A plurality of holes are built in the wall of the VBR™, transverse to the longitudinal axis. A row of holes in one or more of the cylinders is threaded to accept a set screw which, when tightened, serves to prevent further movement (distraction, retraction, or turning) of the VBR™ once the desired height has been achieved. The holes and the hollow core also allow for packing of bone grafting materials to help promote a solid fusion. A ring of small spikes or teeth on each end of the device serves to grip the endplates of the adjacent vertebrae for resisting expulsion.

The VBR™ is manufactured from titanium alloy (Ti6Al4V) which conforms to ASTM F136-92 and ISO 5832/3 standards.

The VBR™ is available in different sizes. Diameters of 20-28 mm with distraction lengths from 25 mm to 130 mm have previously been cleared (K003155). This current submission covers additional diameters ranging from 12 mm to 16 mm and distraction lengths from 10 mm to 65 mm, to better match patients' anatomical requirements.

The VBR™ is for single patient use and is offered for sale non-sterile. They must be sterilized prior to use. Detailed information regarding the VBR™ is provided in Part IV – Device Description. Information regarding sterilization is provided in Part V – Sterilization Information.

5. Intended Use/Indications
The VBR™ is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

The VBR™ is intended to be used with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. Such systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the VBR™ is optional.

6. Technical Comparison
The VBR™ with the smaller diameter sizes (12 – 16 mm) is similar to the previously cleared VBR™ in K003155 and to the Rezaian Spinal Fixator in terms of design and technical characteristics. The VBR™ and Rezaian devices are cylindrically shaped implantable devices that are distractible and retractable by means of rotating the center component. Each of these devices has a ring of small spikes which serves to grip the endplates of the adjacent vertebrae for resisting expulsion. They are also similar in dimensions. The VBR™ with the smaller diameters is also substantially equivalent to the DePuy Acromed Stackable Cage System.

7. Performance Data
   Mechanical testing and a clinical study have been conducted on the VBR™ with the smaller diameters to show equivalence to predicate devices and demonstrate its capability to withstand *in vivo* loads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

Ms. Kim Thurman
Project Leader, Regulatory Affairs
Osteotech, Inc.
51 St. James Way
Eatontown, New Jersey 07724

Re: K012254
Trade/Device Name: VBR™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: July 17, 2001
Received: July 18, 2001

Dear Ms. Thurman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

L. Indications for Use Statement

510(k) Number (if known): K012254
Device Name: VBR™

Indications for Use:

The VBR™ is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

The VBR™ is intended to be used with supplemental internal spinal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. Such systems include posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the VBR™ is optional.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012254